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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,558	07/13/2005	Richard Frank Tester	08830-0307US1	2680

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EXAMINER	
PALENIK, JEFFREY T	

ART UNIT	PAPER NUMBER
1615	

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06/02/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,558	TESTER ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-12,16-19 and 25-37* is/are pending in the application.

4a) Of the above claim(s) *6,17-19 and 26-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-12,16 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE APPLICATION

Applicants' amendments and remarks, filed 23 January 2009 regarding Application N° 10/517,558, are acknowledged and entered on the record. The Examiner acknowledges the following:

APPLICANTS' PETITION

Applicants' Petition from Requirement of Restriction, also filed 23 January 2009. Applicants petitioned to have new claims 36 and 37 included with Groups I and III, respectively, and to have Groups I and III rejoined for examination on the merits. The Decision on Petition, mailed 20 February 2009, summarily states that the petition is "granted in-part" such that claims 36 and 37 are now placed within their respective Groups. However, the rejoinder of Groups I and III was denied since a lack of unity remained between the Groups. Furthermore, the species election where it pertains to the buccal-melt and thin film species in the elected Group I was withdrawn and replaced with the three species outlined within the Decision (see pg. 6), wherein Species (i) is directed to claims 4, 5, 7, 16 and 25; species (ii) to claim 6; and species (iii) to claim 36. Regarding the newly set-forth species, claims 6 and 36 are withdrawn from consideration as being directed to non-elected species as are the claims of the remaining Groups II through IV.

Claims 2 and 23 are newly cancelled. Claims 13-15, 20-22 and 24 were cancelled prior to the previous Office Correspondence.

Claims 4 and 25 have been amended. Dependent claim 4 has been amended to remove the term "type" from the limitations. Claim 25 has been amended to depend directly from

independent claim 1, particularly since claim 23, from which it previously depended, has been cancelled.

No new claims have been added.

No new matter has been added.

Thus, claims 1, 3-5, 7-12, 16 and 25 now represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

One new Information Disclosure Statements (IDS), filed on 4 December 2008, is acknowledged and has been reviewed.

WITHDRAWN OBJECTIONS/REJECTIONS

Rejection under 35 USC 112

Applicants' amendment to claim 4, as discussed above, renders moot the rejection to claims 4 and 5, under 35 USC 112, second paragraph. Thus, said rejection stands **withdrawn**.

MAINTAINED REJECTIONS

The following rejection is maintained from the previous Office Correspondence dated 19 August 2008 since the art which was previously cited continues to read on the amended limitations.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-12, 16, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaper et al. (EP 0 242 913 A2) in view and Burgoyne et al. (USPN 6,046,185). It should be noted that the EP patent to Kaper et al. as well as Kaper et al. (USPN 4,780,149) are of the same patent family both derive foreign priority from NL 8600937.

The instant claims 1, 2, 23 and 25 are directed to a bioadhesive pharmaceutical formulation comprising an active agent and a mucoadhesive carrier for said agent wherein the carrier is β-limit dextrin (BLD). Claims 2 and 23 both recite limitations to the composition of claim 1 wherein BLD is obtainable by hydrolyzing starch. Such a limitation is interpreted by the Examiner as being a product-by-process limitation, which per MPEP §2113, holds no patentable weight. Claim 25 recites that "a waxy starch" as the source material for the product-by-process limitation of claim 23. Since this is further limiting a limitation which holds no patentable

weight, it follows that the limitation of claim 25 also holds no weight. Claim 3 further limits the active agent to a pharmaceutically active agent. The composition is recited as being in the form of a buccal-melt product (claim 4) which is further limited to a wafer (claims 5 and 16) and also recited as a thin-film (claims 7 and 16). Herein, and for the purposes of examination on the merits, the Examiner broadly and reasonably interprets a wafer as being a form of or species of a thin film. Claims 8-10 recite the composition of claim 1 as further comprising at least one carbohydrate in the form of alginate, pectin or either of their derivatives. Claims 11 and 12 recite weight percent limitations of alginate within the composition.

Kaper et al. teach a method of making gum-like confections which use a BLD containing food and pharmaceutical products such as confections having a gum structure in addition to other forms such as tablets and deep-freeze products (claims 8 and 9; col. 4, lines 5-13). BLD is taught as being used as both an adhesive carrier or as both a carrier and a binder (col. 4, lines 13-19). Claim 1 teaches that the composition also includes the polysaccharide α-amylase.

Kaper et al. does not teach the inclusion of pectin, alginate or either of their derivatives as the additional carbohydrate components. Nor is it expressly taught, despite the teaching of "a gum structure", that said structure is in the form of a thin film or wafer.

Burgoyne et al. teach a pharmaceutical composition containing a 6,7-dioxygenated steroid compound in admixture with a pharmaceutically acceptable carrier (col. 127, lines 61-65). Said composition is taught as being administered via mucosal tissue using oral, sublingual, vaginal and intranasal routes, wherein the pharmaceutical composition becomes bioavailable upon administration to a patient (col. 128, lines 6-14). Solid forms of the composition are taught

as including powders, granules, tablets, capsules, chewing gum, wafers or the like, as well as multiple inert diluents or edible carriers such as gelatin binders, dextrin excipients, and alginate-based disintegrants (col. 128, lines 37-54).

Burgoyne neither expressly teaches the use of the β-limit form of dextrin nor the percent weight ranges for alginate in the composition.

However, in view of the combined teachings of the prior art, one of ordinary skill in the pharmaceutical or nutritional art, at the time of the invention, would have been motivated to combine an adhesive carrier comprising a dextrin-based compound such as β-limit dextrin with at least one additional carbohydrate and a pharmaceutically active agent in order to achieve the instantly claimed bioadhesive pharmaceutical formulation. Such would have been obvious in the absence of evidence to the contrary since both Kaper and Burgoyne teach mucoadhesive wafer-like structures which comprise pharmaceutically active agents coupled with dextrin-based carriers and at least one additional carbohydrate component. Chewing gum structures, which are practiced by both inventions, are buccally (e.g. orally) administered compositions which are very well known in the art as having many different forms, particularly a wafer or ribbon form as evidenced by Garbutt (USPN 2,156,810; col. 1, lines 9-12; claim 1).

Therefore, a person of ordinary skill in the art would have a reasonable expectation of success in modifying the solid pharmaceutical dosage form practiced by Burgoyne et al. in view of the β-limit dextrin adhesive carrier compound practiced by Kaper et al., since the combined teachings disclose the instantly claimed bioadhesive pharmaceutical formulation.

Neither reference expressly teaches the percent weight ranges for alginate in the composition, as claimed by the Applicants. Since the values of each parameter with respect to the claimed composition are adjustable, it follows that each is a result-effective parameter that a person having ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill, to adjust the amount of alginate or alginate derivative within the composition particularly in light of its role as disintegrating agent as taught by Burgoyne et al. (col. 128, lines 48-50) in order to best control and/or achieve the desired drug release profile. Optimization of the alginate percentage is further supported in light of the teaching of Burgoyne, wherein said drug is also capable of being optimized by an artisan of ordinary skill in the art (col. 128, lines 21-24). Thus, absent some demonstration of unexpected results from the claimed parameters, optimization of any of these parameters would have been obvious at the time of Applicant's invention.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1, 3-5, 7-12, 16 and 25 under 35 USC 103(a) as being unpatentable over the combined teachings of Kaper et al. (EP 0 242 913 A2 or USPN 4,780,149) and Burgoyne et al. (USPN 6,046,185) have been fully considered but they are not persuasive.

Applicants allege that the combined teachings of Kaper and Burgoyne do not include bioadhesive formulations, do not suggest or teach the use of β-limit dextrin (BLD) as a mucoadhesive carrier, and do not make mention of wafer-like structures. Applicants further

allege that Burgoyne does not refer to BLDs in any form, and makes no mention of bioadhesive or mucoadhesive properties. Applicants further traverse the rejection on the grounds that the "claimed alginate concentrations differ substantially from the concentrations of alginate that would typically be used when the alginate is employed as a disintegrating agent" (Remarks, pg. 8, last paragraph).

In response, the Examiner respectfully submits that claim 1 is directed to a bioadhesive formulation comprising BLD and an active agent, which is discussed above as being expressly taught by the combined references. The bioadhesive and mucoadhesive properties recited by claim 1, are just that, properties, and until some material differences are demonstrated, said limitation is considered by the Examiner as being directed toward the instantly claimed composition.

Regarding Applicants' allegation that there is no mention of wafer-like structures, the Examiner respectfully points to the rejection whereby Kaper expressly teaches the production of a gum-like confection as an example of a prepared pharmaceutical product (claims 8 and 9, col. 4, lines 5-10). Preparation of the formulations of Kaper into "wafer-like" products is further made obvious as evidenced by the teachings of Garbutt et al., as discussed above.

Lastly, regarding Applicants' allegation against the optimization of the alginate, the Examiner respectfully that neither the Kaper nor Burgoyne references expressly teach the instantly claimed percent range of alginate. However, Kaper does expressly teach that the pharmaceutical product, which may have a confectionary gum structure, will also comprise a mixture of BLD and maltose, which functions as a binder (e.g. adhesive) (col. 4, lines 5-19). The method of preparing and applying BLD containing a starch hydrolysate as practiced by

Kaper further teaches that the confectionary mixture which may be used may comprise 40-80 wt% BLD as well as 20-60 wt% of maltose. Though Kaper does not teach the use of alginate, the combined teachings of Kaper and Burgoyne suggest that alginate (e.g. sodium alginate) is an excipient (e.g. disintegrating agent) which may be substituted for the maltose employed by Kaper. This is further evidenced by the invention practiced by Kono et al. (USPN 4,748,032), which expressly teaches that maltose and alginate are functionally equivalent conventionally employed carbohydrates used to prevent deterioration of comestible products (col. 3, lines 63-68).

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

NEW REJECTIONS

In light of Applicants' amendment to claim 25, the following rejection have been newly added:

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation "in which the starch" in the second line of the claim. There is insufficient antecedent basis, as presently amended, for this limitation in the independent claim. As such, amended claim 25 is interpreted as reciting the same subject matter as the independent claim, particularly since the remaining limitation was previously directed to a product-by-process limitation (cancelled claim 23).

All claims have been rejected; no claims are allowed.

CONCLUSION

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615